

**Medicare Preventive Services
Medicare Lifestyle Modification Program Demonstration
Federal Register Notice - January 5, 2000**

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[Notices]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3028-N]

Medicare Program; Notice of the Solicitation for Proposals To
Expand the Medicare Lifestyle Modification Program Demonstration

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces our solicitation for proposals to expand the Medicare Lifestyle Modification Program Demonstration to one additional, national multi-site cardiovascular lifestyle modification program. The purpose of this demonstration is to test the feasibility and cost-effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. This demonstration will test proven and intensive programs designed to reduce or reverse the progression of cardiovascular disease of patients at risk for invasive treatment procedures. The expansion will allow for a comparison between two different lifestyle modification models across several factors, including price. The demonstration began October 1, 1999 and will be conducted over a 4-year period. Currently, the demonstration is being implemented at several sites subscribing to one multi-site lifestyle modification program model. Enrollment for each multi-site program is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy specific clinical admission criteria.

DATES: Letters of Intent: Letters of Intent must be received by the HCFA project officer by February 4, 2000.

Proposals: Proposals (an original and 5 copies), each with a copy of the timely letter of intent, must be received by the HCFA project officer by April 4, 2000.

ADDRESSES: Letters of Intent and Proposals: Department of Health and Human Services, Health Care Financing Administration, Attention: Armen Thoumaian, Ph.D., Project Officer, Medicare Lifestyle Modification Program Demonstration, Office of Clinical Standards and Quality, Mail Stop: S3-02-01, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Demonstration Website: www.hcfa.gov/quality/qlty-3.htm.

FOR FURTHER INFORMATION CONTACT: Armen Thoumaian, Ph.D., (410) 786-6672, or e-mail Athoumaian@hcfa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Problem

Research has provided evidence that specific lifestyle changes can lead to a decrease in the levels of cardiovascular risk factors, resulting in lower morbidity and mortality associated with coronary artery disease (CAD). Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. The programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion.

Studies have shown that controlling single risk factors such as a low-fat diet, smoking cessation, exercise, or stress management are beneficial in the treatment of cardiovascular disease. Other psychosocial risk factors, including depression and social isolation, have already been shown to be important. Multi-factorial risk reduction programs that include reduction of some or all of these risk factors in a comprehensive cardiovascular lifestyle management program, however, have yet to be evaluated for their effectiveness or long-term cost savings in the Medicare population.

We currently pay for 12 weeks of cardiac rehabilitation services for Medicare patients who have a prior diagnosis of myocardial infarction or who have had a recent cardiac revascularization procedure or both. Coverage under the Medicare cardiac rehabilitation benefit is more limited than that contained in a comprehensive lifestyle modification program. We are investigating the benefits of covering a complete package of services offered under an

established, national multi-site lifestyle modification program. Lessons learned from this demonstration will provide us with information needed to explore the possibility of providing this type of program as an alternative to more customary medical management (for example, medications, angioplasty, and heart bypass surgery) when medication is not effective.

B. Demonstration Description

Through our Office of Clinical Standards and Quality (OCSQ), we published a notice in the Federal Register that announced our implementation of a demonstration to evaluate the feasibility and cost-effectiveness of cardiovascular lifestyle modification (64 FR 53394, October 1, 1999). The demonstration period began on October 1, 1999 and will provide a 3-year enrollment period ending on October 1, 2002, with payment through September 30, 2003 (for a total of 4 years). Enrollment in the demonstration is limited to Part B eligible Medicare beneficiaries who meet specific clinical criteria that document significant cardiovascular disease.

There are many cardiovascular lifestyle modification programs across the country. Each varies in program length, treatment services offered, and program cost. Few of these programs have published results about their success in reducing coronary artery disease. This demonstration began at sites licensed to conduct the 12-month long Dr. Ornish Program for Reversing Heart Disease . These facilities offer a cardiovascular lifestyle modification program where the treatment length and the type and amount of services offered are standardized. In addition, although limited, there are published studies about this program that provide some degree of evidence of its success in reducing or reversing the progression of cardiovascular disease in patients who complete the program. Beginning a demonstration with these facilities was a logical choice to provide a standard of care and quality oversight for Medicare beneficiaries. The standardized program also means that a single price can be negotiated for program enrollment across the sites. Total enrollment for this multi-site program is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy clinical admission criteria.

C. Clinical Criteria for Beneficiary Enrollment Under the Demonstration

Under this Medicare demonstration, we pay for a package of specific services that we do not cover under the regular Medicare program. Under these circumstances, the appropriateness of care provided is of obvious concern. The criteria for enrollment in the demonstration reflect clinical standards to ensure the services offered can provide the most appropriate and beneficial treatment to those enrolled. We are

interested in a treatment from which the Medicare patient can experience a measurable and immediate benefit with a potential for a lifetime benefit. In this case, we are interested in treatment that brings about the reversal of coronary artery occlusion, amelioration of symptoms from coronary artery disease, or some other positive, observable change in the patient's condition. We require that the Medicare beneficiaries who meet the clinical criteria for enrollment under the demonstration will be only people with substantial CAD.

The program sites selected for this demonstration must add specific requirements to their admission screening criteria. First, patients participating in the demonstration must have Part B Medicare eligibility at the time of enrollment. Second, we require the following four clinical criteria under the demonstration for enrollment of Medicare beneficiaries:

1. The presence of angina as a medical condition for each Medicare beneficiary.
 2. One of the following diagnostic studies, which demonstrate clinically significant ventricular myocardium at risk for infarction (EKG/stress testing/angina surveys without additional imaging studies will not be accepted):
 - a. Coronary angiogram (with estimated ejection fraction) demonstrating lesions in certain vessels--
 - Greater than 70 percent left anterior descending coronary artery (LAD).
 - Greater than 70 percent right coronary artery (RCA).
 - Greater than 70 percent left circumflex coronary artery.
 - Greater than 50 percent left main coronary artery.
 - b. Reversible perfusion defect on nuclear imaging study.
 - c. Inducible wall motion abnormality on stress echo.
 - d. Cardiac positron emission tomography (PET) scan with rubidium-82 showing perfusion defect.
 3. The beneficiary's physician must have recommended that, as an option, the beneficiary undergo revascularization (coronary artery bypass graft (CABG) or angioplasty) in the near future. The beneficiary's physician must be comfortable that the beneficiary is clinically stable to undergo comprehensive lifestyle changes as an alternative intervention.
 4. The beneficiary must be willing to make these comprehensive lifestyle changes.
- Finally, a beneficiary with any of the following clinical criteria is excluded from participating in the demonstration:
1. Acute myocardial infarction within the 2-week period before enrollment.
 2. Left main disease greater than 50 percent occlusion.
 3. Three-vessel disease with decreased ejection fraction.
 4. Unstable angina.

5. CABG surgery within 4 weeks of enrollment (unless otherwise approved for participation by his or her physician).
6. Previous angioplasty within 6 months of enrollment.
7. Hypotensive response to exercise (greater than 20 mm Hg drop in systolic pressure).
8. History of exercise-induced ventricular tachycardia or third degree heart block without evidence of current stability.
9. Non-ischemic cardiomyopathy (EF less than 40 percent), without evidence of significant CAD.
10. Class IV congestive heart failure (CHF).
11. History of malignant ventricular arrhythmia or use of automatic implantable defibrillator.
12. Residence beyond 90 minutes commuting time to the program site.
13. Significantly impaired cognitive function (for example, dementia).
14. Potentially fatal co-morbidity (for example, metastatic cancer) and unlikely to survive 1 year after entrance into the project.

The selected demonstration sites of the multi-site program must assure that the criteria for inclusion have been met and that none of the exclusion criteria are present for any Medicare beneficiary seeking enrollment in the program. In addition, each beneficiary's personal physician must certify that the beneficiary meets the clinical eligibility requirements to participate in the cardiovascular lifestyle modification program before the beneficiary enrolls in the program.

D. Quality Monitoring and Evaluation

The continuous monitoring of the quality of care delivered to Medicare beneficiaries undergoing lifestyle modification and a continuous assessment of possible health risks to individual beneficiaries are essential during this demonstration. We have contracted a Medicare Peer Review Organization to provide continuous quality monitoring of the demonstration sites to help assure the safety of Medicare patients. In addition, we will conduct an evaluation of the demonstration through a separate contract with an independent research firm to determine the feasibility and cost-effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. The evaluation will compare the outcomes of Medicare beneficiaries participating in the demonstration with other Medicare beneficiaries, matched according to disease severity and other characteristics, who are receiving more customary treatments for coronary artery disease. Specifically, we are interested in comparing the outcomes of beneficiaries who go through the demonstration with Medicare beneficiaries who are recommended for re-vascularization but initially opted for medical management. Demonstration sites selected must cooperate with the quality monitoring and review contractor and

the evaluation contractor.

II. Provisions of This Notice

A. Purpose

We are interested in expanding the Medicare Lifestyle Modification Program Demonstration. The expansion will allow us to compare different lifestyle modification models across several factors, including price. We are limiting the expanded demonstration to one additional, national multi-site cardiovascular lifestyle modification program offering a 12-month multi-disciplinary clinical outpatient program of lifestyle modification services to Medicare beneficiaries through a program currently provided to the general public. We will pay for a program of lifestyle modification treatment services for up to 1,800 Medicare beneficiaries diagnosed with severe CAD who enroll before October 1, 2002.

This notice announces our solicitation for proposals from established, national multi-site lifestyle modification programs having the characteristics listed in section II.B. of this notice. All interested offerors must provide a full description of their program characteristics, so that we can make an award determination based on the organization, the quality and safety of the program, and the capability to recruit a sufficient number of Medicare beneficiaries. A Letter of Intent and Proposal from the parent entity licensing, franchising, or otherwise representing the multi-site lifestyle modification program are required as described in sections II.B. and II.C. of this notice.

We will negotiate a fixed payment rate with an entity representing all of the licensed sites participating in the parent program. We will present sites licensed by the parent program with the negotiated rate agreement and demonstration protocol and ask them to consider participating in the demonstration. We will ask those sites that agree to participate to enter into individual agreements with us to abide by the terms and conditions for participation in the demonstration. Demonstration sites will receive the negotiated fixed rate (absent inflationary adjustments) for the completed program. We will monitor quality and evaluate the demonstration as described earlier to determine if this service would benefit the Medicare population.

Under the demonstration, we will pay all approved sites of the multi-site program 80 percent of the negotiated fixed payment amount for the complete treatment episode when a beneficiary completes the 12-month program. If there is a beneficiary disenrollment from the program before completing the 12-month program, we will pay the demonstration site a pro-rated portion of the total payment for that beneficiary. This payment amount will apply to treatment at all participating

demonstration sites in the multi-site program and remain fixed during the demonstration period. The demonstration site may collect the remaining 20 percent of the fixed payment amount from the beneficiary as a program or enrollment fee. Under the demonstration, an individual site may elect to waive this fee, but if it chooses to do so, it must waive it for all Medicare beneficiaries who enroll in the demonstration. As part of the proposal, applicants must propose an all-inclusive payment amount for the complete 12-month lifestyle modification program to be offered to Medicare beneficiaries. The selectee must cooperate with quality monitoring efforts and the formal evaluation of the demonstration. We will provide no additional funding.

B. Letter of Intent

An organization that believes it meets the requirements of section II.C. of this notice must submit a Letter of Intent to submit a Proposal. The signed Letter of Intent must be received by the HCFA project officer by the date in the DATES section of this notice. The Letter of Intent must indicate the applicant's intention to submit a completed Proposal for the demonstration. Submitting a Letter of Intent does not obligate the applicant to submit a Proposal. The letter must be signed by a duly authorized official and include the following information about the applicant:

- Name.
- Address.
- Contact person.
- Business telephone number.
- All existing HCFA provider number(s).
- An Employer Identification Number (EIN) for basic identification purposes.

The HCFA project officer, or designee, will contact the specified representative (contact person) for each timely submitted Letter of Intent to discuss the application process. Organizations that submit a timely Letter of Intent must submit a completed original Proposal and 5 copies (along with a copy of the previously submitted Letter of Intent) to the HCFA project officer by the date in the DATES section of this notice.

C. Proposals of Eligible Organizations

The offeror must provide information describing the nature of its program, how it is perceived as innovative, and any scientifically based evidence supporting the success of its program in reducing the need for inpatient invasive procedures. We are interested in Proposals

from a national, multi-site lifestyle modification program that can satisfy the requirements of this section. We will consider only proposals that are responsive to the requirements for submission under this solicitation. Proposals must be no more than 45 pages in length, including appendices and attachments. Our technical review panel will review and consider only those Proposals that we receive by the date in the DATES section of this notice and for which we receive a timely Letter of Intent.

A program that wishes to be considered for this payment demonstration must submit a Proposal that includes evidence of the following:

1. The existence of a parent organization that has developed, designed, and continuously monitored its program. The parent organization must have legal responsibility for the licensing of its affiliates and must provide to its licensees all proprietary, clinical, marketing, and administrative materials. A standardized package of instructions must be available in the form of manuals, audiotapes, and videotapes and must be provided to all sites as part of the licensing arrangement.
2. A list of multiple sites or affiliates that are located in various geographic locations throughout the United States and that use the parent organization's name and are recognized as entities of the parent organization. The parent organization must provide initial on-site training to all affiliated staff and schedule regular on-site visits to ensure adherence to the prescribed regimen.
3. A standardized protocol that describes the program in detail and includes a prescription of a low-fat diet, lifestyle counseling, nutrition education, supervised exercise, stress management training, group support, and smoking cessation. In addition, the protocol must provide for medical lipid management. The protocol must have a defined treatment plan that provides the length of the regimen and the sessions (by frequency and time). Patient and staff goals must be specified. The manual must contain a description of staffing needs, educational requirements, and the roles and responsibilities of all personnel.
4. A formal management plan that describes the coordination of reporting and communicating to the affiliated sites (for example, regular phone conferences, annual or bi-annual retreats, and electronic messaging). A recognized program or site coordinator must act as a liaison at the parent site to provide guidance and address issues that arise during day-to-day operations.
5. A minimum of 3 years of continuous operation using the standardized protocol. Affiliates must have a minimum of 1 year of experience in providing the same standardized services and should be recognized as a part of, or operate under, a larger corporate entity that is a Medicare provider.
6. A record of successful marketing of its program to, or its use

by, the age 65 and over population, including the under-served and minority populations.

7. A record of successful patient adherence to the program.
8. Coverage by a minimum of one major private insurer.
9. The capability or potential of receiving and transmitting information electronically between its sites and HCFA.

This notice is not covered by the Paperwork Reduction Act of 1995 and accordingly was not reviewed by the Office of Management and Budget. In accordance with Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

We have examined this notice in accordance with Executive Order 13132, Federalism, and have determined that it will not have any negative impact on the rights, roles, or responsibilities of State, local, or Tribal governments.

Authority: Sections 402(a)(1)(G) and (a)(2) of the Social Security Amendments of 1967 (Public Law 90-248), as amended (42 U.S.C. 1395b-1(a)(1)(G) and (a)(2)).

(Catalog of Federal Domestic Assistance Program No. 93.779; Health Financing, Demonstrations, and Experiments)

Dated: December 15, 1999.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.
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